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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,860	11/28/2000	Andrew Welcher	99,372-A	9408

20306 7590 12/31/2002

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EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 12/31/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/724,860

**Applicant(s)**

WELCHER ET AL.

**Examiner**

Janet L Andres

**Art Unit**

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,8,10,11 and 43-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,8,10,11 and 43-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 13 November 2002 is acknowledged. Upon further consideration, the finality of the previous office action is withdrawn. It is noted that a Notice of Appeal has been filed. Applicant can request a refund for the associated fees or leave it as credit for future appeals. Claims 1-8, 10, 11, and 43-45 are pending and under examination in this application. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

#### ***Claim Rejections Withdrawn***

2. The rejection of claims 1-8, 10, 11, and 43-45 under 35 U.S.C. 112, second paragraph, is withdrawn in response to Applicant's amendment.

#### ***Claim Rejections Maintained/New Grounds of Rejection***

3. Claims 1, 2, 4-8, 10, 11, and 43-45 are newly rejected under 35 U.S.C. 112, first paragraph, as lacking written description. These claims encompass allelic variants. Such variants are molecules that exist in nature and have particular sequences. The instant specification does not set forth these sequences and there is no other way to identify them. Thus one of skill in the art would not conclude that Applicant was in possession of allelic variants at the time of filing.

4. The rejection of claims 1-8, 10, 11, and 43-45 under 35 U.S.C. 112, first paragraph, as lacking enablement commensurate with the scope of the claims is maintained for reasons of record in the office action of paper no. 13.

Applicant argues that an increase in protein tyrosine phosphorylation occurs in response to the polypeptide. Applicant argues that this a particular functional limitation. Applicant points

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to the phosphorylation of particular signaling molecules in response to interferons. Applicant argues that such phosphorylation is a well-established functional characteristic of interferons. Applicant argues that one of skill in the art could make and recognize molecules with this function. Applicant has amended the claims to require that the invention have this function.

Applicant's arguments have been fully considered but have not been found to be persuasive, and Applicant's amendment is insufficient to overcome this rejection.

The increase in JAK phosphorylation that occurs in response to interferons is, as Applicant points out, directly associated with a known signaling pathway that results in well-known functions. However, what Applicant claims and what Applicant has disclosed is not phosphorylation of particular molecules associated with signaling, but merely an increase in tyrosine phosphorylation. Such an increase does not provide a particular functional limitation; as stated previously, tyrosine phosphorylation occurs in response to many different stimuli and does not indicate any particular function. In addition, the claims still contain the limitation of "antigenic". This is also not a particular functional limitation; this is not a particular property of interferons or any other molecules. Thus, amending the claims to recite "tyrosine phosphorylation" instead of "phosphorylation" does not overcome the rejection.

5. The rejection of claims 1-8, 10, 11, and 43-45 under 35 U.S.C. 112, first paragraph, as lacking written description is maintained for reasons of record in the office action of paper no.

13.

Applicant argues that tyrosine phosphorylation plays a well-recognized role in interferon signaling and is a functional characteristic of interferons.

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Applicant's arguments have been fully considered but have not been found to be persuasive. As stated above, what is characteristic of interferons is JAK phosphorylation. What is disclosed in the instant specification is merely a general increase in protein tyrosine phosphorylation, identified by Western blotting with an anti-phosphotyrosine antibody. Such increase phosphorylation occurs in response to many different molecules, unrelated to interferons. Thus it is not a particular characteristic of an interferon-like molecule and cannot be used to identify such a molecule. Additionally, as stated above, antigenicity is not a particular characteristic of interferons. The ability to generate antibodies is not specific to interferon-like molecules or any other class of molecules.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that


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sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.  
Patent Examiner

December 17, 2002

  
YVONNE EYLER, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600